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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1614

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4

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/068,633	ALI ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-12 and 25 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12 and 25, drawn to a composition comprising an aliphatic alcohol having from 1-4 carbon atoms; a thickening agent; and a neutralizer.
  - II. Claims 13-24, drawn to a method of preparing a high alcohol skin sanitizing composition of Group I.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). A review of US 6165457, US5167950 makes clear that the product as claimed can be made by another and materially different process.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent

literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Mr. Skoglund, Rodney on April 10, 2003 a provisional election was made to prosecute the invention of Group I, claims 1-12 and 25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **DETAILED ACTION**

##### ***Status of application***

5. Claims 1-25 are pending.
6. The elected claims 1-12 and 25 are presented for the examination and the non-elected claims 13-24 are withdrawn from the consideration.

##### ***Claim Rejections - 35 USC § 112***

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recited a neutralizer designated by the FDA as a direct food substance that is Generally Recognized As Safe. However, FDA guideline is not permanent wherein the said neutralizer is considered to be a relative term which renders the claim indefinite. Since it lacks the consistency where it fails to provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the claims 1-6 are properly included in this rejection.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lins(US 5,167,950).

The claims 1-12 and 25 are directed to the composition comprising an aliphatic alcohol having from 1 to 4 carbon atoms such as ethanol(about 60-90 weight

percent); a thickening agent such as carbomer polymer(about 0.1-5%); and an effective amount of a neutralizer such as sodium hydroxide.

US'950 teaches a composition having a high alcohol content used as an antiseptic. The patent(US'950) contemplates several examples(1-19, columns 10-19) comprising about 52-75 weight percent of an alcohol such as ethanol or isopropyl(see column4, lines 63-65); about 0.1-1.5 weight percent of gelling agent such as carbomer (see column 5, lines 15-48 and column 6, lines 12-15); 0.5-10% of neutralizing agents for thickening agent such as sodium hydroxide or triethanolamine(see column 5, lines 49-column 6, lines 7 and column 4, lines 18-20) and other ingredients such as fragrances or moisturizer, see column 8, lines 27-52. US'950 teaches all the critical elements required by the instant claims except the limitations recited in claims 10-11(i.e. viscosity and density, respectively) . As to the said limitations regarding viscosity and density, same viscosity and density should be possessed by the patented invention because both patented invention and the instant claimed invention use the very same essential ingredients so that one would have envisaged that both inventions share same physical properties inherently.

Thus, it is considered to be that all the claimed subject matter is taught by the cited reference and the claims are properly included in this rejection.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lins(US 5,167,950).

Lins' teaching is mentioned immediately above in 102 rejection (supra).

Although Lins teaches sodium peroxide as a neutralizer(see column 7, line 50), Lins fail to contemplate the exemplified composition using sodium peroxide as a neutralizing agent that is required in applicant's claim 25. However, it would have been obvious to one of ordinary skill in the art to substitute triethanolamine(TEA) with sodium peroxide because they are functionally equivalent as suggested by the cited reference, see column 7, lines 49-50. One would have been motivated to so because it is always desired to have more selection option to enhance the efficiency of manufacturing process and the patient satisfaction.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lins (US 5,167,950) in view of BFGoodrich tech. Disclosure( "Neutralizing carbopol.....", 1998).

Lins' teaching is mentioned immediately above in 102 rejection (supra).

Although Lins teaches various neutralizers(see column 7, lines 49-column 6, lines 7), Lins fail to teach arginine as a neutralizing agent that is required in applicant's claim 8. However, it would have been obvious to one of ordinary skill in the art to substitute triethanolamine(TEA) or sodium peroxide which is taught by Lins with arginine because they are functionally equivalent and effective as suggested by the cited reference(BF Goodrich), see figure 4. One would have been motivated to so

because it is always desired to have more selection option to enhance the efficiency of manufacturing process and the patient satisfaction.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

### ***Conclusion***

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
April 10, 2003  
Art unit 1614